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Indian Standard REAFFRED THE

SPECIFICATION FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER

(Second Revision)

UDC 66:048:36:615:471



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INDIAN STANDARDS INSTITUTION MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG **NEW DELHI 110002**



AMENDMENT NO. 3 AUGUST 1998 TO

IS 3830: 1979 SPECIFICATION FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER

(Second Revision)

(Page 4, clause 2.1) — Substitute the following for the existing clause:

'2.1 Various components of water stills shall be made from stainless steel sheet conforming to designation 02Cr19Ni10 or, 07Cr18Ni904Cr17Ni12Mo2 as specified in Table 1 of IS 6911: 1992*. The sheet used for manufacturing the components shall be of 2B finish as specified in IS 6911: 1992*. The minimum sheet thickness shall be 0.5 mm. The permissible reduction in thickness due to deep drawing shall be 0.15 maximum.'

(Page 4, foot-note) — Insert the following foot-note:

(MHD 14)

^{**}Specification for stainless steel, plate, sheet and strip (first revision)."

AMENDMENT NO. 1 OCTOBER 1983 TO PROPERTY OF THE PROPERTY OF TH

S:3830-1979 SPECIFICATION FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER

(Second Revision)

Corrigendum

(Page 6, clause 6.3, line 6) - Substitute '1.4 times' for '14 times'.

(CPDC 14)

Reprography Unit, ISI, New Delhi, India



AMENDMENT NO. 2 SEPTEMBER 1984

TO

IS:3830-1979 SPECIFICATION FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER

(Second Revision)

<u>Alterations</u>

(Page 4, clause 2.2) - Substitute the following for the existing clause:

'2.2 Stop-cock and valves shall be made from stainless steel conforming to any designation as specified in IS:6603-1972† or from gun metal conforming to IS:306-1968‡ or grade 1 or 2 of IS:318-19815.'

(Page 4, clause 4.1, last sentence) - Substitute the following for the existing sentence:

'The joints shall be ground smooth from inside and polished smooth.'

(Page 4, clause 4.2) - Substitute the following for the existing clause:

'Baffle - The baffle shall have adequate cross sectional area for vapour to pass through. The constructional features of the baffle shall facilitate multiple directional changes for entrainment separation.

(Page 4, foot-note) - Substitute the following for the existing foot-note with '†' mark:

**Specification for stainless steel bars and flats.

'\$Specification for tin bronze ingots and castings (second revision).

'Specification for loaded tin bronze ingots and castings (second revision).'

(CPDC 14)

Indian Standard

SPECIFICATION FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER

(Second Revision)

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(Continued on page 2)

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(Continued from page 1)

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Indian Standard

SPECIFICATION FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER

(Second Revision)

O. FOREWORD

- **0.1** This Indian Standard (Second Revision) was adopted by the Indian Standards Institution on 30 April 1979, after the draft finalized by the Hospital Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.
- 0.2 The use of water stills for production of pyrogen-free distilled water is becoming very common in hospitals, dispensaries and pharmacological laboratories. In this revision use of materials other than stainless steel have been deleted.
- 0.3 The problem of explosion risk arising from anaesthetic vapours have not been taken into consideration on the understanding that the stills dealt with in this standard will be generally installed away from operation theatres. Installation of these stills in an operation theatre is not recommended.
- 0.4 If the raw water for feeding to the still is hard, a water softening plant should be installed to soften the water before using it in the still.
- 0.5 In order to get efficient performance, it is considered essential that the waterhead which serves the water still should be fixed at a height between 3 and 9 m.
- **0.6** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS: 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

^{*}Rules for rounding off numerical values (revised).

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1. SCOPE

1.1 This standard covers water stills used for the production of pyrogenfree distilled water used in the preparation of injectible solutions.

2. MATERIALS

- 2.1 Various components of water stills shall be made from stainless steel sheet conforming to designation 04Cr18Ni10, 07Cr18Ni9 or 04Cr17Ni12 Mo2 as specified in Table 1 of IS: 6911-1972*. The components shall be of 2B finish as specified in Table 8 of IS: 6911-1972*. The nominal thickness of sheet shall be 0.5 mm. The permissible reduction in thickness, due to deep drawing shall be 0.15 mm maximum.
- 2.2 Stop-cock and valves shall be made from stainless steel conforming to any designation as specified in IS: 6603-1972†.

3. SHAPE AND CAPACITY

- 3.1 Shape of the water still shall preferably be cylindrical or elliptical with the ends fitted at the bottom of the evaporator. They may be placed horizontally or vertically. The evaporator of the still shall be provided with an opening to permit access to the inside for cleaning or descaling, when necessary.
- 3.2 Water still shall have the capacity as agreed to between the manufacturer and the purchaser and it shall be capable of giving distillate output (in litres/hour) within \pm 10 percent of the rated output.

Note — For determination of the output (in litre/hour) the raw water temperature shall be between 20 to 30°C.

4. CONSTRUCTION

- 4.1 Evaporator Evaporator shall be placed horizontally or vertically and shall be of cylindrical, elliptical, or semi-elliptical cross section with rounded corners. All welded joints shall be welded by argon are process or with appropriate flux coated electrodes. The joints shall be ground smooth from inside, surface descaled and polished.
- 4.2 Baffle Baffles shall be made dished and perforated.
- 4.3 Condenser Condenser shall be surface type, shell and tube type or coiled type. It shall be designed with the provision for cleaning the surface exposed to raw water used for cooling (for the removal of scales). Condenser shall be provided with inlet and outlet for cooling

^{*}Specification for stainless steel plate, sheet and strip.

[†]Specification for stainless steel bars and flats.

water and vent for removal of dissolved gases. The condenser shall be designed on the basis of cooling water requirement which shall not exceed the proportion of 12 litres cooling water per litre of distilled water for any of the sizes (see 3.2).

- 4.3.1 Cooling water inlet to the condenser shall be provided with a stop-cock.
- **4.4 Mounting** Still may be supported on stand or wall-mounted but in either case the material used for mounting shall be sufficiently sturdy to give satisfactory service.
- 4.4.1 Evaporator of stills should be provided with constant level arrangement and either light and sight glasses or level indicator. Electrically heated water stills may be provided with automatic cut-off arrangement for the heater in case of failure of water supply to the boiler, at the option of the buyer.

4.5 Fittings

- 4.5.1 Overflow and Drain An overflow arrangement shall be provided, which shall maintain the water level in the evaporator. A drain connection shall be provided leading to drain funnel with an air gap.
- 4.5.2 Bleeder Valve If the design so justifies, a bleeder valve may be fitted outside the evaporator 6 to 8 mm above the overflow level.

5. STORAGE TANK

- 5.1 At the option of the purchaser, a storage tank (of capacity as may be ordered) shall be provided with the water still. Distillate from the still shall directly enter the tank, which shall be enough to store four hours' output of the distillate from the water still.
- 5.1.1 The tank shall be cylindrical, with an air-tight lid, inside joints ground smooth, rounded and placed horizontally or vertically. The joints shall be welded by argon arc process or with appropriate flux coated electrodes and shall be ground smooth.
- 5.1.2 The tank shall have a gauge glass, an inlet for the distillate and a draw-off and drain connection. The draw-off connection shall be at least 25 mm above the top of the electric heater or steam coil, as the case may be.

6. PERFORMANCE

6.1 Heating — Stills of capacity up to 40 litres shall be either electricor steam-heated. Capacity higher than 40 litres should preferably be steam-heated.

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- 6.2 Electric Heating Electric heaters shall be of immersion type and in multiples of a single unit as far as possible and shall be according to IS: 368-1963* or IS: 4159-1976†.
- 6.3 Steam Heating Heating surface of the tubes fitted to the evaporator shall be designed for operating at a pressure not exceeding 700 kPa (7 kgf/cm² approx). The steam outlet shall have a steam trap and the inlet a pressure gauge, a safety valve and a stop-cock. The safety valve shall be set to operate within +15 percent of the steam inlet pressure. Steam consumption per hour shall not exceed 14 times the output of distilled water. At the option of the buyer, suitable arrangement shall be provided to use the steam condensate generated during heating as feed water to the evaporator.
- 6.4 Storage tank shall be provided with suitable heating arrangement with temperature control device to maintain the temperature of distillate at minimum of 60°C.
- 6.5 At the option of the buyer, units for production of double or triple distillation may be provided where distilled water produced will be used as the feed water for the next still. Suitable arrangement for easy dismantling device for interconnecting pipes shall be provided.
- 6.5.1 The cooling water of the second unit shall not enter the evaporator, but shall be drained directly in case of double distillation unit.
- 6.5.2 The cooling water of the second and third units shall not enter the evaporator, but shall be drained directly in case of triple distillation unit.
- 6.6 At the option of the buyer, suitable level control arrangement may be provided whereby distilled water production can be controlled automatically according to the level of distilled water in the storage tank.

7. MARKING

- 7.1 Each still shall be legibly and indelibly marked with the following:
 - a) Identification of the manufacturer;
 - b) Code and serial number;
 - c) Wattage, voltage, phase and cycle in the case of electrically operated stills;
 - d) Cooling water temperature;
 - e) Capacity of the still; and
 - f) Maximum and minimum inlet pressure of steam coils, in direct steam operated stills.

^{*}Specification for electric immersion water heaters (revised), †Specification for mineral filled sheathed heating elements (first revision).

7.1.1 Each still may also be marked with the ISI Certification Mark.

Note — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

- 7.2 Each still shall be accompanied by a manual which shall contain the following information:
 - a) Instructions and plan for installation of the still (including minimum and maximum floor area required),
 - b) Operation of the still, and
 - c) Routine maintenance and service.

8. PACKING

8.1 The still shall be packed as agreed to between the manufacturer and the purchaser.

6. TEST

- 9.1 The quality of distillate shall conform to the Indian Pharmacopoeia requirements for 'water for injection'.
- 9.1.1 For collecting sample of distilled water from the still for purposes of testing, the procedure given below shall be followed:
 - a) Allow water to run out for about 10 to 15 minutes;
 - b) Collect directly from outlet of the still, about 500 ml of distilled water in sterile, clean glass stoppered container (sterile container used for collecting the sample shall be washed in freshly distilled water before sterilization); and
 - c) Sterilize it immediately at 121°C (equal to 100 kPa pressure approx) for about 30 minutes. Allow to cool to room temperature and test.

INTERNATIONAL SYSTEM OF UNITS (SI UNITS)

Base Units

QUANTITY	Unit	Symbol
Length	metre	m
Mass	kilogram	kg
Time	second	•
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

QUANTITY	Unit	Symbol	
Plane angle	radian	rad	
Solid angle	steradian	sr	

Derived Units

QUANTITY	Unit	SYMBOL	DEFINITION		
Force	newton	N	$1 N = 1 \text{ kg.m/s}^2$		
Energy	joule	J	I J = I N.m		
Power	Watt	W	1 W 🕳 1 J/s		
Flux	weber	Wb	1 Wb = 1 V,s		
Flux density	tesla	T	$1 T = 1 Wb/m^2$		
Frequency	hertz	Hz	$1 H_2 = 1 c/s (s^{-1})$		
Electric conductance	siemens	S	I S = I A V		
Electromotive force	volt	v	1 V = 1 W/A		
Pressure, stress	pascal	Pa	$1 Pa = 1 N/m^2$		

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